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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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June 6, 2003

WARNING LETTER

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. William Terhar
President
Ocean Beauty Seafoods, Inc.
P.O. Box 70739
1100 West Ewing Street
Seattle, Washington 98107

Ref: #-DEN-03-17

Dear Mr. Terhar:

On March 19 through 24, 2003, investigators from the Denver District office of the Food and Drug Administration conducted an inspection of your seafood processing facility at 1911 South 900 West, Salt Lake City, Utah, and found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4).

The deviations cause your sushi rolls, fresh/frozen tuna, ready-to-eat smoked salmon and crab meat to be adulterated in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation, and the FDA Fish and Fisheries Products Hazards and Controls Guidance through links on FDA's homepage at http://www.fda.gov .
The deviations observed were as follows:

1. You must implement the record keeping system that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the:

   a. Receiving Fresh critical control point to control scombroid toxin formation as listed in your HACCP plan for "Sc[]ombroid Species." Specifically, the presence of gel packs or ice, and core temperature were not recorded upon receipt of scombroid species on Grade Sheet records for September 16, 2002, and September 24, 2002.

   b. Cooler Storage critical control point to control scombroid toxin formation as listed in your HACCP plan for "Sc[]ombroid Species." Specifically, there are no records documenting the monitoring of ice as required by your HACCP plan.

   We acknowledge your April 4, 2003, response to these observations stating that monitoring observations are now being documented. The effectiveness of these corrections will be evaluated during our next inspection of your firm.

2. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4).

   a. However, your firm's HACCP plan for "Cooked/Ready To Eat" products lists a monitoring procedure at the "Receiving Fresh" critical control point that is not adequate to control the food safety hazards of pathogen growth and toxin formation.

      The procedure that you have listed includes monitoring the presence of gel packs or ice upon receipt, and monitoring the core temperature of products upon receipt. However, your "Cooked/Ready To Eat" products are routinely received in trucks that are not packed with gel packs or ice. Your monitoring procedure needs to address how continuous monitoring is to be accomplished during transport when ice or gel packs are not used.

      We acknowledge receipt of your FDA-483 response dated April 4, 2003. However, your proposed corrective action for this observation to verify the receiving temperature of cooked ready-to-eat products "periodically" is not adequate. It is important that proper temperature be continuously maintained during transport of microbiologically sensitive product. When refrigeration is provided by ice or gel packs, the ice or gel packs can be checked on receipt. However, when you receive product without gel packs or ice, you need to ensure continuous temperature control during mechanical refrigeration, such as by using time-temperature indicators to monitor possible temperature abuse during transit. The proposed monitoring procedure of periodic internal temperature checks at receiving does not ensure temperature control during transport.

b. However, your firm's HACCP plan for "Seafood Sushi" products lists a monitoring frequency at the "Storage Refrigerated" critical control point of a minimum of [redacted] per day during plant operation that is not adequate to control the food safety hazards of pathogen growth and histamine formation.

   Since your finished product sushi is stored under mechanical refrigeration, we suggest that you install a high temperature alarm or some method of continuous temperature monitoring, such as a temperature data logger. Once you have modified the monitoring procedure at the "Storage Refrigerated" critical control point, you must take steps to implement the listed monitoring procedures.

3. You must adequately implement the monitoring procedures that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). The monitoring procedures that you have listed in your HACCP plan for "Cooked/Ready To Eat" products at the "Storage Room" critical control point include monitoring temperature using a sensory thermometer; this procedure as written is adequate, however, the scale and time increments used for recording temperature data are inadequate because they do not allow for accurate assessment of temperature at a given time.

4. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm does not monitor the required eight elements of sanitation to ensure control in the processing of ready-to-eat product.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline how you will correct these deviations. You should include in your response documentation such as revised HACCP plans, production or monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: William H. Sherer, Compliance Officer, P.O. Box 25087, Denver, CO 80225. If you have any questions regarding any issue in this letter, please contact Mr. Sherer at (303) 236-3051.

Sincerely,

Howard E. Mamura for
Acting Director

B. Belinda Collins
Director, Denver District

cc: Mr. Dan R. Samson
General Manager
Ocean Beauty Seafoods, Inc.
1911 South 900 West
Salt Lake City, UT 84104